PHYSICOCHEMICAL PROPERTIES

Report

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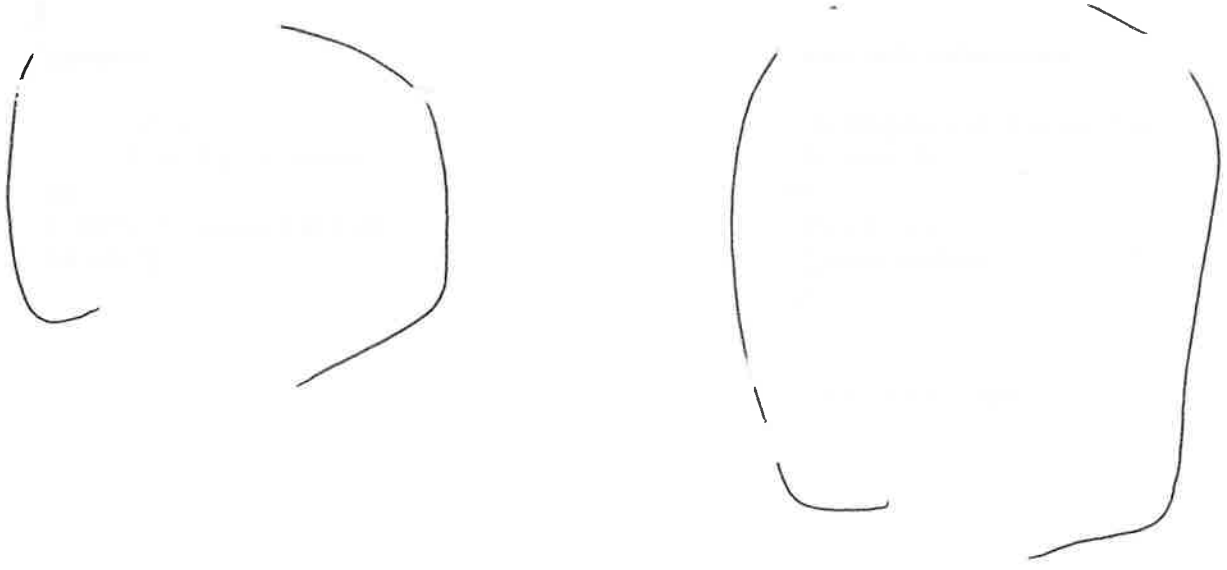


CONTENTS

COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

Physicochemical Properties

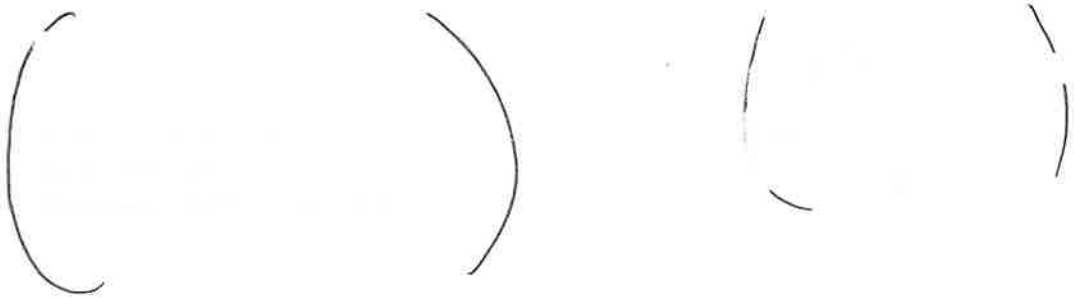
The study described in this report was conducted in compliance with the following Good Laboratory Practice standards and I consider the data generated to be valid.

The UK Good Laboratory Practice Regulations (Statutory Instrument 1999 No. 3106, as amended by Statutory Instrument 2004 No. 994).

EC Commission Directive 2004/10/EC of 11 February 2004 (Official Journal No. L 50/44).

OECD Principles of Good Laboratory Practice (as revised in 1997), ENV/MC/CHEM(98)17.

These principles of Good Laboratory Practice are accepted by the regulatory authorities of the United States of America and Japan on the basis of intergovernmental agreements.



QUALITY ASSURANCE STATEMENT

Physicochemical Properties

The following inspections and audits have been carried out in relation to this study:

Study Phase	Date(s) of Inspection	Date of Reporting to Study Director and Management
Protocol Audit	25 August 2004	25 August 2004
Report Audit	15-16 June 2005	16 June 2005

Process based inspections: At or about the time this study was in progress inspections of procedures employed on this type of study were carried out. These were conducted and reported to appropriate Company Management as indicated below:

Process Based Inspections	Date(s) of Inspection	Date of Reporting to Management
Phase transition	21 January 2005	21 January 2005
Physical characteristics	15 March 2005	15 March 2005

In addition, an inspection of the facility where this study was conducted was carried out on an annual basis. These inspections were promptly reported to Company Management.

CONTRIBUTING SCIENTISTS

Physicochemical Properties

The following staff member has reviewed this report.

SUMMARY

A study was performed to determine the pour point and relative density of . The methods followed are amongst those described in the Annex to EEC Directive 92/69/EEC and the OECD Guidelines for the Testing of Chemicals.

The pour point of was determined to be 81°C (EEC Method A1, OECD Method 102).

The relative density of was determined to be 1.07 (EEC Method A3, OECD Method 109).

INTRODUCTION

A study was performed to determine the pour point and relative density of [redacted]. The methods followed are amongst those described in the Annex to EEC Directive 92/69/EEC (Methods A1 and A3) and the OECD Guidelines for the Testing of Chemicals (Methods 102 and 109).

The protocol was approved by the [redacted] on 20 August 2004, and by the Sponsor on 14 September 2004.

The experimental start and completion dates were 31 May 2005 and 3 June 2005 respectively.

Location of study [redacted]

TEST SUBSTANCE

Identity:

Appearance:

Storage conditions:

Lot number:

Expiry date:

Purity:

Date received:

POUR POINT
(EEC Method A1, OECD Method 102)

METHOD

Given the resinous nature of the test substance, a pour point test was conducted in preference to a melting or freezing point test.

The pour point was determined according to ASTM Test Method D97-87.

DEFINITION AND UNITS

The pour point is defined as the lowest temperature (°C) at which the test material is observed to flow when cooled and examined under the prescribed conditions of this procedure.

APPARATUS

Cloud and pour point apparatus, Stanhope Seta Ltd.

PROCEDURE

A cylindrical glass jar was filled to a specified mark with the test substance and the jar sealed using a cork fitted with an ASTM 61C/IP63C thermometer. After heating to approximately 90°C in a waterbath, the jar was placed in (but insulated from) a metal jacket contained within a further waterbath (maintained at 24°C). At 3°C intervals, the jar was removed from the jacket, tilted to check for sample movement and then returned to the jacket, the procedure being performed in 3 seconds. When no initial movement was observed, the jar was held in a horizontal position for 5 seconds, and the sample examined. The process was repeated until no movement was observed when the sample was held in the horizontal position for 5 seconds. The procedure was conducted in duplicate.

RESULTS

The pour point, defined as the lowest temperature at which the test material was observed to flow, was found to be 81°C, mean of 81°C and 81°C.

CONCLUSION

The pour point c as found to be 81°C.

RELATIVE DENSITY
(EEC Method A3, OECD Method 109)

METHOD

The relative density of the test substance was determined relative to purified water using a pyknometer at 20°C. Aqueous Tween 80 (0.1% v/v) was employed as the displacement liquid.

DEFINITION AND UNITS

The relative density (D_4^T) of solids and liquids is defined as the ratio of the mass of a volume of substance to be examined, determined at T°C, and the mass of the same volume of water at 4°C.

APPARATUS

Analytical balance:	Model RC 210P, Sartorius Instruments
Pyknometer:	Glass, nominal 25 cm^3 capacity at 20°C, fitted with capillary stopper

REAGENTS

Water:	Purified by reverse osmosis and deionising; Elga Maxima
Displacement liquid:	0.1% v/v aqueous Tween 80

SUITABILITY OF DISPLACEMENT LIQUID

The suitability of 0.1% v/v Tween 80 as a displacement liquid was confirmed by the observation that approximately 10 mg of the test substance did not dissolve in 10 ml of this vehicle (solubility < 0.1% w/v). The relative density of 0.1% Tween 80 has been determined to be 0.998 at 20°C, i.e. the same as pure water.

PROCEDURE

Test temperature: 20°C

To a clean, dry and accurately weighed pyknometer (w_1), test substance (approximately 1 g) was added. The pyknometer was re-weighed (w_2). The pyknometer was then filled with displacement liquid and weighed again (w_3). The weight of the pyknometer containing only displacement liquid was also recorded (w_4).

Two tests were performed concurrently using separate pyknometers.

Parameters:

mass of pyknometer empty (g) = w_1

mass of pyknometer + test substance (g) = w_2

mass of pyknometer + test substance + 0.1% v/v Tween 80 (g) = w_3

mass of pyknometer + 0.1% v/v Tween 80 (g) = w_4

Calculations:

mass of 0.1% v/v Tween 80 to fill pyknometer (g) = $w_4 - w_1 = W_1$

mass of test substance (g) = $w_2 - w_1 = W_2$

mass of 0.1% v/v Tween 80 to fill pyknometer containing W_2 g test substance (g) = $w_3 - w_2 = W_3$

mass of 0.1% v/v Tween 80 equivalent to W_2 g test substance (g) = $W_1 - W_3 = W_4$

volume of W_2 g test substance (ml) = $W_4 / (\rho_w^T) = V_s$

relative density of test substance = $W_2/(V_s \times \rho_w^4) = D_4^T$

where ρ_w^T is the density of 0.1% v/v Tween 80 at the temperature of determination (0.998 g/ml)

ρ_w^4 is the density of water at 4°C (= 1.000 g/ml)

D_4^T is the relative density of the test substance at the test temperature compared to water at 4°C

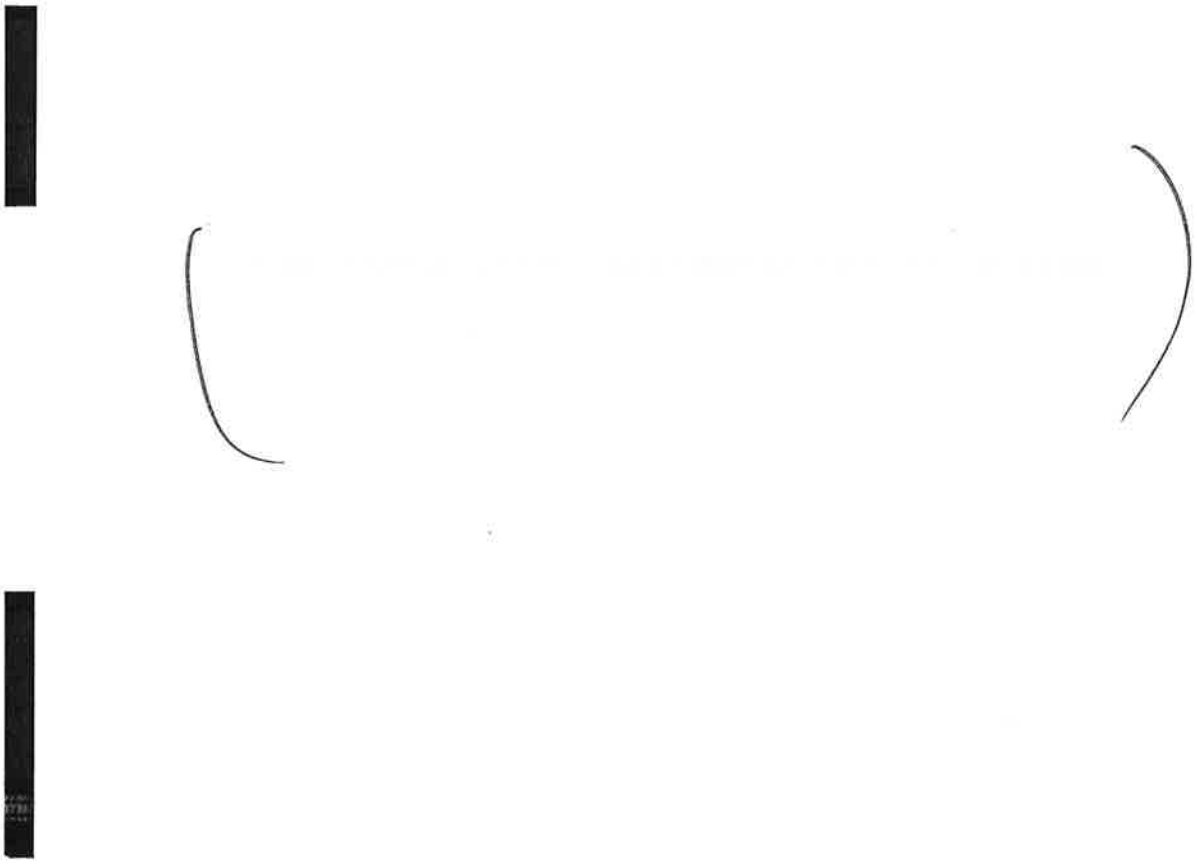
RESULTS

Parameter	Determination 1	Determination 2
w_1	18.06176	21.75179
w_2	19.06626	22.75958
w_3	43.93957	46.68675
w_4	43.86472	46.62182
W_1	25.80296	24.87003
W_2	1.00450	1.00779
W_3	24.87331	23.92717
W_4	0.92965	0.94286
V_s	0.93151	0.94475
D_4^T	1.08	1.07
$\bar{x}\ D_4^T$	1.07	

CONCLUSION

The relative density (D_4^{20}) o was found to be 1.07.

APPENDIX 1



THE DEPARTMENT OF HEALTH OF THE GOVERNMENT OF THE UNITED KINGDOM

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE
IN ACCORDANCE WITH DIRECTIVE 88/320 EEC

LABORATORY

[redacted]

TEST TYPE

Analytical Chemistry
Ecosystems
Environmental Fate
Environmental Toxicity
Mutagenicity
Toxicology
Phys/Chem Tests

DATE OF INSPECTION
22nd April 2003

A general inspection for compliance with the Principles of Good Laboratory Practice was carried out at the above laboratory as part of UK GLP Compliance Programme.

At the time of the inspection no deviations were found of sufficient magnitude to affect the validity of non-clinical studies performed at these facilities.

Roge G. Alexander
25/7/03

Dr. Roger G. Alexander
Head, UK GLP Monitoring Authority

APPENDIX 2

Department of Health

THE DEPARTMENT OF HEALTH OF THE GOVERNMENT OF THE UNITED KINGDOM

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE
IN ACCORDANCE WITH DIRECTIVE 2004/9/EC

TEST TYPE

Analytical Chemistry
Clinical Chemistry
Ecosystems
Environmental Fate
Environmental Toxicity
Mutagenicity
Toxicology
Phys/Chem Testing

DATE OF INSPECTION

12th April 2005

A general inspection for compliance with the Principles of Good Laboratory Practice was carried out at the above laboratory as part of the UK GLP Compliance Programme.

At the time of inspection no deviations were found of sufficient magnitude to affect the validity of non-clinical studies performed at these facilities.

Bryan J. Wright 9/6/05

Mr. Bryan J. Wright
Head, UK GLP Monitoring Authority